

**REMARKS****Amendments**

Claims 1, 5-8, 12, and 16-19 are amended herein in order to clarify the meaning of the claim. The specification is amended at page 3 also to clarify the invention. No new matter is added by these amendments. Support for the amendments can be found as follows:

**Claim 1:** page 4, lines 11-13, which recites that **“p63 detection may be employed in any differential diagnosis between a tumor of squamous origin, differentiation or squamous potential, and a tumor without squamous origin, differentiation or squamous potential.”** Accordingly, no new matter has been added by these amendments.

**Claim 5:** no support required, two elements of a Markush group are removed from the claim.

**Claims 6-8:** “cancer” is changed to “carcinoma”—see specification at page 3, lines 5-14.

**Claim 16:** the original claim as filed, which recites in the penultimate phrase “or a carcinoma without squamous differentiation potential”, and page 4, lines 11-13, as per claim 1 above.

**Claims 17-19:** the order of the claims was rearranged or support is found in the original claims.

The specification has been amended on page 3, under Summary of the Invention, to recite that the method is used to distinguish between an epithelial carcinoma with squamous potential and either an epithelial carcinoma *without* squamous differentiation or differentiation potential or a non-epithelial cell tumor. The original language erroneously indicated that this distinction was between an epithelial squamous cell carcinoma from a **non-epithelial cell carcinoma**. This is a clear error, since a carcinoma by definition is an epithelial cell tumor (see attached Exhibit A). As such, there can be no such thing as a non-epithelial cell carcinoma. By contrast, non-epithelial-derived tumors



The Examiner contends that the Groups are unrelated, and alleges that it can be shown that they are not disclosed as capable of use together or have different modes of operation since they are differentially classified according to the Patent Office classification system.

In order to be responsive to the restriction/election requirement, Applicants herein elect **with traverse** the Group I claims 1-7, directed (as amended) to a method of distinguishing differentiated squamous from undifferentiated lung carcinoma on the basis of p63 expression.

The restriction requirement is traversed in part. Applicants assert that at least the claims of at least **Group IV**, claims 16-19, be rejoined and examined along with the claims of **Group I**. Claims 16-19 are directed to a method of distinguishing among epithelial tumor types with or without squamous differentiation (or differentiation potential), based on the presence or absence of p63. Claim 16 is generic to the method of the Group I claims, which specifically recite that the differentiation is between a squamous (or potentially squamous) **lung** carcinoma and a non-squamous or non-potentially squamous **lung** carcinoma.

Therefore, if the method of determining if the tumor cell is a squamous epithelial tumor or a non-squamous epithelial tumor based on p63 expression is free from the prior art (e.g., using a search employing the terms “p63 and squamous epithelial tumor”), then the specific organ from which the tumor is derived such as lung or cervix should be irrelevant-the claimed method will be novel for **all** epithelial tumors.

### Species Election

In addition to the restriction requirement among groups of claims, the Examiner requires an election of species within the Group I claims. Specifically one of the following species must be elected: poorly- differentiated squamous cell carcinoma, moderately-differentiated squamous cell carcinoma; well-differentiated squamous cell carcinoma, adenosquamous carcinoma, and adenocarcinoma. The Examiner contends that the species are patentably distinct from each other.

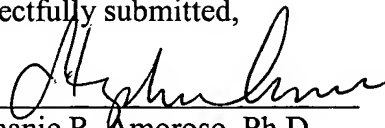


In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Dated: September 24, 2004

Respectfully submitted,

By



Stephanie R. Amoroso, Ph.D.

Registration No.: 51,401

DARBY & DARBY P.C.

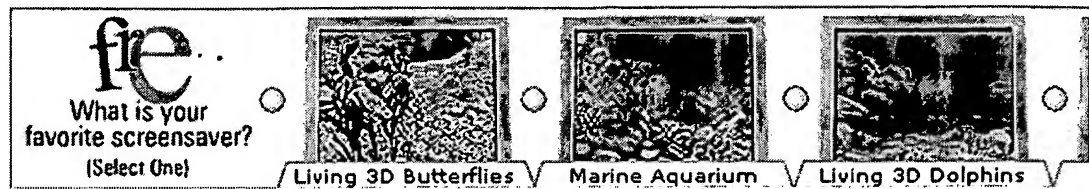
P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorneys/Agents For Applicant



## Carcinoma

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### Webster's 1913 Dictionary

car'ci'nō'ma Pronunciation: kār'sī'nō'mā

**n. 1. (Med.)** A form of malignant cancer arising from epithelial tissue. The term was earlier applied to all forms of certain non-malignant forms. It is contrasted with sarcoma, a malignant form of cancer arising from connective tissue. See Cancer.

### WordNet Dictionary

**Noun 1. carcinoma** - any malignant tumor derived from epithelial tissue; one of the four major types of cancer

### Wikipedia

In medicine, **carcinoma** is any malignant cancer that arises from epithelial cells, as opposed to a sarcoma which connective tissue.

### Types of carcinoma

- *Adenocarcinoma* is cancer that starts in cells of glandular (secretory) tissue that lines some internal organ:
- *Basal cell carcinoma*
- *Adenoid cyctic carcinoma*
- *Heptocellular carcinoma*
- *Adenocortical carcinoma*
- *Oat cell carcinoma*\* *Squamous cell carcinoma*
- *Renal cell carcinoma* is a form of kidney cancer.

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### Related Words

benign tumor, callosity, callus, cancer, corn, cyst, excrescence, fungosity, fungus, growth, intumescence, malignant neoplasm, nevus, nonmalignant tumor, outgrowth, proud flesh, sarcoma, tumor, verruca, wart, wen

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